



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 5, 2018

David Chi
Regulatory Affairs Manager
Monsanto Company
800 North Lindbergh Blvd.
St. Louis, Missouri 63167

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment –

- Modify the designations for the active and inactive ingredients;
- Removal of Trecepta™ RIB Complete® corn blend as an Alternate Brand Name;
- Make minor changes to the Directions for Use.

Product Name: MON 89034 x MIR162 Seed Blend
EPA Registration Number: 524-626
Application Dates: 3/29/2018
OPP Decision Numbers: 542190

Dear Mr. Chi:

In an application dated March 29, 2018 (OPP Decision No. 542190), you notified the U.S. Environmental Protection Agency (EPA) that you requested to modify the designations for the active and inactive ingredients, to remove Trecepta™ RIB Complete® corn blend as an Alternate Brand Name, and to make minor changes to the Directions for Use. Subsequently, the EPA determined that the actions requested do not fall under the scope of Pesticide Registration Notice (PRN) 98-10 and therefore converted the notification to a non-PRIA amendment (OPP Decision No. 542190). The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

Additionally, Trecepta™ RIB Complete® corn blend has been removed from the registration. Our records have been updated accordingly. This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling

or subsequently approved labeling. “To distribute or sell” is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to your company’s website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Matt Weiner by phone at 703-347-0333 or via email at weiner.matthew@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Alan Reynolds', written in a cursive style.

Alan Reynolds, Team Leader
Emerging Technologies Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

Plant-Incorporated Protectant Label

MON 89034 × MIR162 Seed Blend

Lepidopteran-Protected Corn
(OECD Unique Identifier: MON-89Ø34-3 × SYN-IR162-4)

Active Ingredients:

Bacillus thuringiensis Cry1A.105 and the genetic material (vector PV-ZMIR245) necessary for its production in MON 89034 × MIR162 corn (OECD Unique Identifier: MON-89Ø34-3 × SYN-IR162-4).....≤0.0059%*

Bacillus thuringiensis Cry2Ab2 and the genetic material (vector PV-ZMIR245) necessary for its production in MON 89034 × MIR162 corn (OECD Unique Identifier: MON-89Ø34-3 × SYN-IR162-4).....≤0.0043%*

Bacillus thuringiensis Vip3Aa20 and the genetic material (vector pNOV1300) necessary for its production in MON 89034 × MIR162 corn (OECD Unique Identifier: MON-89Ø34-3 × SYN-IR162-4).....≤0.015%*

Other Ingredients:

Phosphomannose isomerase (PMI) marker protein and the genetic material (vector pNOV1300) necessary for its production in MON 89034 × MIR162 corn (OECD Unique Identifier: MON-89Ø34-3 × SYN-IR162-4)≤0.00068%*

*Percentage (wt/wt) on a dry weight basis for whole plant (forage) of MON 89034 × MIR162 plants.

The MON 89034 × MIR162 seed with this refuge configuration contains 95% MON 89034 × MIR162 mixed with 5% non-*B.t.* corn within a single lot of seed

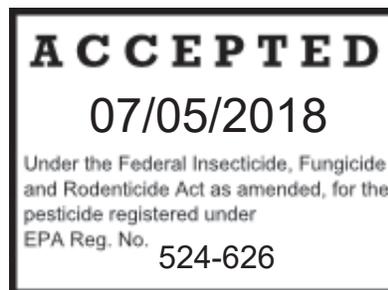
KEEP OUT OF REACH OF CHILDREN

CAUTION

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EPA Registration No. 524-626

EPA Establishment No. 524-MO-002



Monsanto Company
800 North Lindbergh Blvd.
St. Louis, MO 63167

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. Information regarding commercial production as specified in the terms and conditions of this registration must be included in the Technology Use Guide and/or Insect Resistance Management (IRM) Grower Guide.

MON 89034 × MIR162 can be used to protect corn plants from leaf, stalk, and ear damage caused by corn borers and corn earworm.

This plant-incorporated protectant (PIP) may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

Refuge Requirements

A refuge must consist of corn hybrids that do not contain *B.t.* technologies for the control of corn borers and corn earworm. This product achieves the required refuge as the refuge is interspersed within the field and occurs only by planting a licensed seed-mixture containing MON 89034 × MIR162 or MON 89034 × MIR162 stacked with other non-PIP technologies, with a minimum of 5% non-PIP seed. This refuge configuration complies with refuge requirements only in the U.S. Corn Belt.

The sufficiency of this refuge configuration is defined by geography and ultimately is based on insect presence and species. **The seed mix refuge option for MON 89034 × MIR162 complies with refuge requirements only in the U.S. Corn Belt.**

The 95/5% MON 89034 × MIR162 seed mix product may be planted in cotton growing areas; however, planting the 95/5% MON 89034 × MIR162 seed mix in cotton growing areas still requires planting an additional structured refuge of at least 20% corn, which is not a lepidopteran-protected *B.t.* corn hybrid. The refuge may be treated with insecticides, as detailed below, to control lepidopteran stalk-boring and other pests. **The interspersed refuge option for MON 89034 × MIR162 does not alone comply with refuge requirements in cotton growing areas.**

Structured refuge planting options include: separate fields, blocks within fields (e.g., along the edges or headlands), perimeter strips, and strips across the field. External refuges must be planted within ½ mile. When planting the refuge in strips across the field, refuges must be at least four(4) consecutive rows wide.

Cotton-growing areas include the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, and Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, and Sussex), and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, and Stoddard).

The seed mix (interspersed) refuge option under this registration is limited to planting specifically licensed seed corn of MON 89034 × MIR162 and MON 89034 × MIR162 stacks with non-PIP corn.

The field containing an interspersed refuge may be treated with labeled insecticides to control additional corn pests, including larval or adult lepidopteran pests, because both the MON 89034 × MIR162 and refuge are treated in the same manner. Insecticide treatments for control of pests listed on this label may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Microbial *B.t.* insecticides must not be applied to the field containing a seed mix interspersed refuge.

For the sole purpose of manufacturing and small scale research trials for observation, these refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant (PIP) active ingredient per registrant per year.

Corn Insects Controlled or Suppressed

European corn borer	<i>Ostrinia nubilalis</i>
Southwestern corn borer	<i>Diatraea grandiosella</i>
Southern cornstalk borer	<i>Diatraea crambidoides</i>
Corn earworm	<i>Helicoverpa zea</i>
Fall armyworm	<i>Spodoptera frugiperda</i>
Stalk borer	<i>Papaipema nebris</i>
Sugarcane borer	<i>Diatraea saccharalis</i>
Beet armyworm	<i>Spodoptera exigua</i>
True armyworm	<i>Pseudeletia unipuncta</i>
Black cutworm	<i>Agrotis ipsilon</i>
Western bean cutworm	<i>Striacosta albicosta</i>
Lesser cornstalk borer	<i>Elasmopalpus lignosellus</i>
Dingy Cutworm	<i>Feltia jaculifera</i>

Sales of corn hybrids that contain Monsanto's *B.t.* corn plant incorporated protectant must be accompanied by a grower guide which includes information on planting, production, and insect resistance management and notes that routine applications of insecticides to control these insects are usually unnecessary when corn containing the *B.t.* proteins is planted.

MON 89034 × MIR162 seed blend is a product of Monsanto's research program offering unique genetic characteristics for specific grower needs and may be protected by one or more of the following U.S. patents that can be found at <http://www.monsantotechnology.com>